

APPLICATION NO.

FILING L

09/580,463 05/26/00

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9/19/01

Please find below and/or attached an Office communication proceeding.

**Office Action Summary**

Application No.

09/580,463

Applicant(s)

WHEELER, CARL J.

Examiner

Thaian N. Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_.  
2a) This action is FINAL.                    2b) This action is non-final.  
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-46 is/are pending in the application.  
    4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
5) Claim(s) \_\_\_\_ is/are allowed.  
6) Claim(s) \_\_\_\_ is/are rejected.  
7) Claim(s) \_\_\_\_ is/are objected to.  
8) Claim(s) 1-46 are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.  
10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
    If approved, corrected drawings are required in reply to this Office action.  
12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
    a) All b) Some \* c) None of:  
        1. Certified copies of the priority documents have been received.  
        2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
        3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
    \* See the attached detailed Office action for a list of the certified copies not received.  
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
    a) The translation of the foreign language provisional application has been received.  
15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)                    4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_.  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)  
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_                    6) Other: \_\_\_\_\_

## DETAILED ACTION

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20, 24-46 drawn to a composition comprising a cationic lipid compound and a method for delivering a biologically active agent to a cell of an animal and kits containing the composition, classified in class 424, subclass 450, class 435, subclass 458, for example.
- II. Claims 21-23, drawn to a composition comprising a cationic lipid compound and kits containing the composition, classified in class 424, subclass 450, for example.
- III. Claims 1-20, 24-46, drawn to a composition comprising a cationic lipid compound and a method for delivering a biologically active agent to a cell of a plant, classified in class 424, subclass 450, and class 435, subclass 468, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are mutually exclusive and independent. The composition comprising a cationic lipid compound of Invention I is of materially separate and different structure than the composition comprising a cationic lipid compound of Invention II.

Inventions I and III are mutually exclusive and independent. The method for delivering a biologically active agent to a cell of an animal requires materially different and separate protocols than the method for delivering a biologically active agent to a cell of a plant.

Art Unit: 1632

Inventions II and III are mutually exclusive and independent. The composition and kit in Invention II is not required for the method for delivering a biologically active agent to a cell of a plant of Invention III, and vice versa.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Karen Hauda, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-6608. Any administrative or procedural questions should be directed to Patsy Zimmerman, Patent Analyst, at (703) 305-2758. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

Art Unit: 1632

The Group and/or Art Unit location of your application in the PTO has changed.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

*Deborah Crouch*

**DEBORAH CROUCH  
PRIMARY EXAMINER  
GROUP 1632**

**TNT**

Thaian N. Ton  
Patent Examiner  
Group 1632